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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,160	02/06/2002	Dennis Klinman	4239-61997	9731

7590 10/03/2003

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EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,160	KLINMAN ET AL.	
	Examin r	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Inventions 1-21: Claims 11, 12 embrace Inventions 1-21, wherein each of which is directed to a particularly named SEQ ID NO:, classifiable in class 536, subclass 23.1.

Claims 1-10, 13-22 are identified as linking claims for Inventions 1-21.

As such, applicant is required to elected one invention for examination.

Invention 22, Claims 23-41, 52-56, drawn to a general method of inducing an immune response in immune cells or a subject, wherein the method comprises the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 23, Claims 42-44, drawn to a therapeutic method of treating an allergic reaction occurring in a subject, wherein the method comprises the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 24, Claims 42-44, drawn to a preventive method of preventing an allergic reaction occurring in a subject, wherein the method comprises

the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 25, claims 45-47, drawn to a method of enhancing the efficacy of a vaccine, wherein the method comprises the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 26, claims 48-51, drawn to a therapeutic method of treating a disease associated with an immune system in a subject, wherein the method comprises the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 27, claims 48-51, drawn to a preventive method of preventing a disease associated with an immune system in a subject, wherein the method comprises the use of an oligonucleotide having the formula as set forth in claim 1, classifiable in class 514, subclass 44.

Invention 28, claims 57-59, drawn to a method of employing activated antigen presenting cells for inducing an immune response in a subject, classifiable in class 424, subclass 93.21.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-21 are distinct because inventions 1-21 are directed to a specifically named SEQ ID NO: which comprises a specific pattern or arrangement of nucleotide residues, wherein a search of one does not necessarily provide any prior art information for another one as listed in the claims. Furthermore, given the limited resources of the USPTO to conduct prior art search which must cover all of the existing databases of sequences, only up to 2 sequences will be examined in this application, *e.g.,* one sequence as set forth in claim 1 and one sequence as set forth in claims 11 and 12.

Inventions 1-21 and Inventions 22-28 are distinct because the oligonucleotide of claim 1 is not limited for use in any of the restricted methods and can be used as a probe or for one particular method such as a method of inducing an immune response in a cancer patient. Inventions 22-28 are distinct because each of the inventions is drawn to a distinct goal or targeted subject, wherein the targeted subject requires distinct prior art search, consideration and examination for patentability. For example, a preventive method is not the same as a therapeutic method. Also, a method of preventing an allergic reaction is not the same as a method of treating an infectious disease.

Should inventions 1-21 be elected, a Species Restriction to one of the following inventions is required under 35 U.S.C. 121:

The presently pending claims for each of the elected invention are generic to a plurality of disclosed patentably distinct species comprising:

- A specific species of a targeting moiety as listed in claim 20,
- A specific species an immune cell targeted for induction, as listed in claim 24.
- A specific species of a cytokine as listed in claims 30-32.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from the respective claims as listed and cited above, even though this requirement is traversed. The combined features of a particular active agent and/or cytokine and/or carrier, for example, are distinct structurally and would not necessarily overlap with one another when a prior art search is conducted.

Should applicant traverse on the ground that the species are not patentably

distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these species are structurally distinct, and because a search of one does not necessarily overlap with that of an another species, it would be unduly burdensome for the examiner to search and/or consider patentability of all of the claims as presently pending.

Applicant is advised that the response to this requirement to be complete must include an species election of the invention to be examined even though the requirement be traversed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine for patentability of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

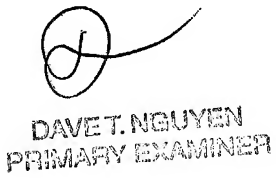
Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.



Dave Nguyen
Primary Examiner
Art Unit: 1632